

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

BAUSCH HEALTH
IRELAND LIMITED, et al.,

Plaintiffs,

v.

MSN LABORATORIES PRIVATE LTD.
et al.,

Defendants.

Civil Action No. 21-10057 (SRC)

OPINION & ORDER

CHESLER, U.S.D.J.

This matter comes before the Court on the motion to amend the Final Pretrial Order (“FPTO”) by Defendants MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc., (collectively, “MSN”). Plaintiffs Bausch Health Ireland Limited and Salix Pharmaceuticals, Inc. (collectively, “Bausch”) have opposed the motion. For the reasons that follow, the motion will be denied.

On this motion, MSN seeks two remedies: 1) relief from part¹ of the parties’ agreement,

¹ The treatise American Jurisprudence 2d states:

A party to a stipulation cannot be relieved of its burdens while holding onto its benefits. Likewise, it has been held that relief may not be granted where it would be partial in nature, leaving the party against whom it was granted wholly or partially bound and at a disadvantage because of having changed his or her position or acted in reliance upon it.

memorialized in the Stipulation approved and filed by this Court on October 1, 2024 (“the Narrowing Stipulation”); and 2) leave to amend the FPTO accordingly.

The parties entered into the Narrowing Stipulation at a point in the litigation at which six *in limine* motions had been fully briefed, and oral argument on these motions had been scheduled, but had not yet occurred. In one of these pending motions, Defendants asked the Court “to exclude Plaintiffs from improperly introducing evidence that MSN infringes the patents-in-suit on the basis of an obsolete specification from MSN’s originally submitted ANDA.” (DE # 236 at 1.) With that *in limine* motion, MSN expressly presented to the Court the problem of how to analyze infringement in a Hatch-Waxman case in which the generic company has submitted a proposed amendment to the originally-filed ANDA, but no information was (or is now still) available as to whether the FDA has allowed the amendment. Neither the Court nor either party knew when or how the FDA might take action on the proposed amendment. In the context of considerable uncertainty about how the infringement analysis in this litigation would play out, the parties both exposed themselves to risk and agreed upon the Narrowing Stipulation, which this Court approved and entered on October 1, 2024. On that same date, at the hearing on the *in limine* motions, the Court presented its resolution of the problem of the infringement analysis and the attempted amendment of the ANDA: the infringement analysis would be based on testing of actual product samples. (Hearing Tr. at 62:12-24.)

MSN seeks relief from its agreement in the Narrowing Stipulation to forego: 1) the defense to infringement that its ANDA product will not meet the “less than 50 ppm acetamide” limitation in claim 1 of the ‘637 patent; and 2) invalidity challenges to four patent claims based on the

argument that the “trifluoroacetic acid (TFA)” limitation is anticipated and obvious. (Defs.’ Opening Br. at 2.)

Now, over one year later, Defendants ask the Court to relieve them from these provisions of the Narrowing Stipulation, and to amend the FPTO accordingly, to prevent manifest injustice. MSN argues that, subsequent to its agreement to the Narrowing Stipulation, two “intervening” events occurred in the litigation: 1) on October 1, 2024, the Court Ordered that the infringement analysis would be based on testing of actual product samples; and 2) in September of 2025, the Court conducted an expedited Markman proceeding and construed the claim term, “trifluoroacetic acid (TFA).” MSN argues:

MSN’s Narrowing Stipulation did not—and could not—have taken into account the Court’s reopening of discovery or subsequent claim construction proceedings. But those subsequent events changed the litigation landscape in ways that MSN could not have anticipated at the time it entered into the Narrowing Stipulation.

...

It would be manifestly unjust to keep MSN bound to the Narrowing Stipulation now that the Court reopened discovery and further construed the patent claims.

(Defs.’ Opening Br. at 1, 4.) The Court is not persuaded, for a number of reasons.

As to the relevant legal standard, Federal Rule of Civil Procedure 16(e) states:

Final Pretrial Conference and Orders. The court may hold a final pretrial conference to formulate a trial plan, including a plan to facilitate the admission of evidence. . . . The court may modify the order issued after a final pretrial conference only to prevent manifest injustice.

MSN’s brief relies on the four-factor analysis stated by the Third Circuit in Waldorf v. Shuta,

142 F.3d 601, 618-19 (3d Cir. 1998). In that case, the Third Circuit held:

We now turn to the Borough’s second argument, that “in exceptional circumstances,” courts will free a party from a stipulation to prevent a manifest injustice. *Kohn*, 458 F.2d at 307; *see also TI Fed. Credit Union*, 72 F.3d at 928. In determining whether there will be manifest injustice unless a party is relieved from a stipulation, courts have focused on such factors as: (1) the effect of the

stipulation on the party seeking to withdraw the stipulation, *see Graefenhain v. Pabst Brewing Co.*, 870 F.2d 1198, 1206 (7th Cir. 1989) (discussing the effect of the stipulation on the party seeking to withdraw the agreement); (2) the effect on the other parties to the litigation, *see Logan Lumber Co. v. Commissioner*, 365 F.2d 846, 855 (5th Cir. 1966) (holding that suitable protective terms or conditions “should be imposed “to prevent substantial and real harm to the adversary” (citations omitted)); (3) the occurrence of intervening events since the parties agreed to the stipulation, *see Bail Bonds by Marvin Nelson, Inc.*, 820 F.2d at 1548 (denying relief from a stipulation because “nothing subsequently occurred to change the effect of the original stipulation”); and (4) whether evidence contrary to the stipulation is substantial, *see Donovan v. Hamm's Drive Inn*, 661 F.2d 316, 317 (5th Cir. 1981) (holding that a court could relieve a party from a stipulation upon a showing of substantial contrary evidence).

Id. In short, MSN fails to persuade that this case presents the exceptional circumstances that justify freeing MSN from the provisions of the Narrowing Stipulation so as to prevent manifest injustice.²

First and foremost, while Defendants acknowledge that Third Circuit law requires a showing that manifest injustice would result from enforcement of the challenged stipulation (see Defs.’ Opening Br. at 4), MSN has failed to demonstrate that holding the parties to their agreement will result in manifest injustice to MSN. Instead of demonstrating manifest injustice, MSN relies on the contention that “subsequent events changed the litigation landscape in ways that MSN could not have anticipated.” (Defs.’ Opening Br. at 1.) MSN asserts: “MSN is harmed by remaining bound to the Narrowing Stipulation under the changed circumstances.” (Id. at 5.) The changed circumstances here are simply that, as the litigation unfolded, the Court made decisions that, MSN states, were unexpected. MSN’s brief does not, however, articulate a

² In short, while MSN has pointed to events that have intervened since it entered into the Narrowing Stipulation, these intervening events are two adverse Court decisions in the litigation; adverse court decisions in litigation are common occurrences in litigation, not exceptional circumstances. Crucially, MSN has not come close to persuading this Court that manifest injustice will result if they are held to the provisions of the Narrowing Stipulation at issue.

rationale which explains why it is manifestly unjust to hold the parties to an agreement made before the Court made two unexpected decisions.

For a litigant to experience unexpected decisions from the Court during the unfolding of litigation is a common event. It is intrinsic to the idea of litigation strategy that, as the litigation proceeds, parties make strategic decisions based on uncertainty about what will happen down the road, and things often turn out differently than one party or the other may have expected. MSN has pointed to no authority for the proposition that forms the foundation of its argument on this motion, that it is manifestly unjust to hold a litigant to commitments it made on the basis of uncertainty about the outcome of the litigation, when things turn out differently than a party may have hoped. MSN has shown no legal basis for this Court to conclude that, under these circumstances, justice requires allowing it to undo a strategic decision made a year ago because the Court subsequently ruled differently than MSN expected.

Examination of the circumstances surrounding the two decisions by the Court that MSN describes as “unexpected” confirms the Court’s view that MSN has not demonstrated manifest injustice.

The first intervening event, MSN contends, is the Court’s decision, stated on the record at the hearing on October 1, 2024, that the infringement analysis in this case would be based on Plaintiff’s testing of product samples from MSN, rather than the terms of the original ANDA. Certainly, this is an intervening event in the case (along with many others), but MSN does not explain how this decision will or may produce manifest injustice, if the Narrowing Stipulation provisions at issue are enforced.³

³ The Court observes that, generally, litigants use various strategies to manage their exposure to

Furthermore, to the extent that MSN contends that manifest injustice arose from the Court's decision to base the infringement analysis on testing of actual product samples, MSN waited over a year to raise the issue and has sat on its rights. MSN's motion appeals to this Court to exercise its equitable powers to prevent injustice, but has provided no explanation for why it waited a year to seek a remedy for an injustice that it argues arose a year ago. By waiting a year to raise the issue, waiting until the eve of trial, the Court finds that MSN has provided no excuse for its delay, and the delay until the eve of trial is manifestly prejudicial to Plaintiffs.

MSN contends that the second intervening event is the Court's recent claim construction decision on the meaning of "trifluoroacetic acid (TFA)." Again, MSN has not explained how this decision will operate to create injustice, if it is held to the contested provisions in the Narrowing Stipulation.⁴

In support of its motion, MSN cites the recent decision in Astellas Pharma Inc. v. Zydus, Inc., 2025 WL 1555219, at *1 (D. Del. May 30, 2025), in which the district court granted a

the risk of adverse judicial decisions in litigation. One such strategy involves entering into a stipulation before the Court issues a decision, as the parties did here: MSN moved *in limine*, seeking a specific solution to the problem of how the attempted ANDA amendment should affect the infringement analysis in this case, but, while it could have waited a few days more to hear the Court's decision on the motion, it decided to agree to a stipulation beforehand. MSN thus made a deliberate choice to enter into the Narrowing Stipulation just a few days before it would appear in Court to argue the related *in limine* motion.

⁴ Plaintiffs, in opposition, point to the timeline of recent events in this case: the Court issued the opinion construing "trifluoroacetic acid (TFA)" on September 26, 2025; MSN agreed to the October 2025 Stipulation, filed October 8, 2025; and MSN filed the letter seeking leave to file the instant motion on October 24, 2025. Plaintiffs contend that, in the October 2025 Stipulation, MSN reaffirmed key aspects of the Narrowing Stipulation. It does appear to be correct that, in the October 2025 Stipulation, MSN affirmed its commitment to a position that it now seeks relief from: MSN will not argue non-infringement of the acetamide limitation in claim 1 of the '637 patent. A few days later, MSN filed its letter seeking to file the instant motion, which would allow it to do the opposite at trial. As Plaintiffs contend, the sequence of events is puzzling.

similar motion for relief from a stipulation in which the generic companies had limited their use of invalidity defenses; the Court gave the movants the requested relief and allowed them to use the defenses that they had agreed to leave out of the case. MSN's brief does not discuss the rationale stated by the Astellas court for granting the motion:

Prejudice to the Generics Manufacturers. Maintaining the stipulation in the consolidated case creates two specific risks to the Generics Manufacturers (and Astellas for that matter). One, following the stipulation risks inconsistent results between defendants and patents. Specifically, two defendants, MSN and Ascent, are already raising an obviousness challenge '780 Patent. If the Court were to find the '780 Patent invalid, it would create an odd situation in which a patent is invalid for one defendant and valid for another. Not only that but Lupin and Zydus are raising an obviousness challenge to the '409 Patent, meaning the jury could come to diverging verdicts on what is, for obviousness purposes, the same patent. A divergence between parties and patents would be unfair to the Generics Manufacturers. Two, following the stipulation encourages unproductive satellite litigation. Lupin and Zydus have suggested that if they are not able to proceed here, they will file a new case for declaratory relief—unbounded by the stipulation. And, if Ascent and MSN succeeds at their bench trial or the jury buys Lupin and Zydus's obviousness arguments, the parties will litigate this issue over again. Finally, if the Court prevents Lupin and Zydus from arguing obviousness and the Federal Circuit reverses, there is a real possibility of a fourth trial on the '780 Patent. Overall, following the stipulation engenders a messier procedural environment and wasted resources for all parties, including Astellas. This unfairness supports reliving Lupin and Zydus of their stipulation.

Id. at *3. MSN points to no similarities between the issues of concern to the Astellas court and the circumstances of the instant case. Astellas is a useful case for contrast and provides no support for granting MSN's motion.

Finally, the Court observes that MSN has not argued that this Court lacked the legal authority to make either of the two intervening decisions, nor that those decisions were themselves substantively or procedurally unjust. Indeed, as the Federal Circuit has noted, the Court is free to conduct a Markman analysis in the proceedings where it is appropriate, even

mid-trial, if necessary.⁵ Here, given the contrary and disputed interpretations of the term “trifluoroacetic acid (TFA)” that appeared in the *in limine* briefs, it became apparent that, unless the Court conducted a supplementary Markman proceeding at that point, it might have to conduct such a proceeding in the middle of the trial, which would be more prejudicial to both parties than the procedure the Court followed. MSN has failed to persuade that it is manifestly unjust to hold MSN to the contested provisions of the Narrowing Stipulation, or that manifest injustice will result if MSN is not allowed to modify the FPTO. Rather, it appears just to continue to enforce all terms in the Narrowing Stipulation, and to deny MSN’s request to amend the FPTO six days before trial. The motion will be denied.

For these reasons,

IT IS on this 4th day of November, 2025

ORDERED that Defendants’ motion to amend the FPTO (Docket Entry No. 441) is
DENIED.

s/ Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.

⁵ As the Federal Circuit held in Papst Licensing GmbH & Co. KG v. Fujifilm Corp. (In re Papst Licensing Dig. Camera Patent Litig.), 778 F.3d 1255, 1261 (Fed. Cir. 2015):

[I]t is worth reiterating that a district court may (and sometimes must) revisit, alter, or supplement its claim constructions (subject to controlling appellate mandates) to the extent necessary to ensure that final constructions serve their purpose of genuinely clarifying the scope of claims for the finder of fact. That determination is to be made as the case moves forward.